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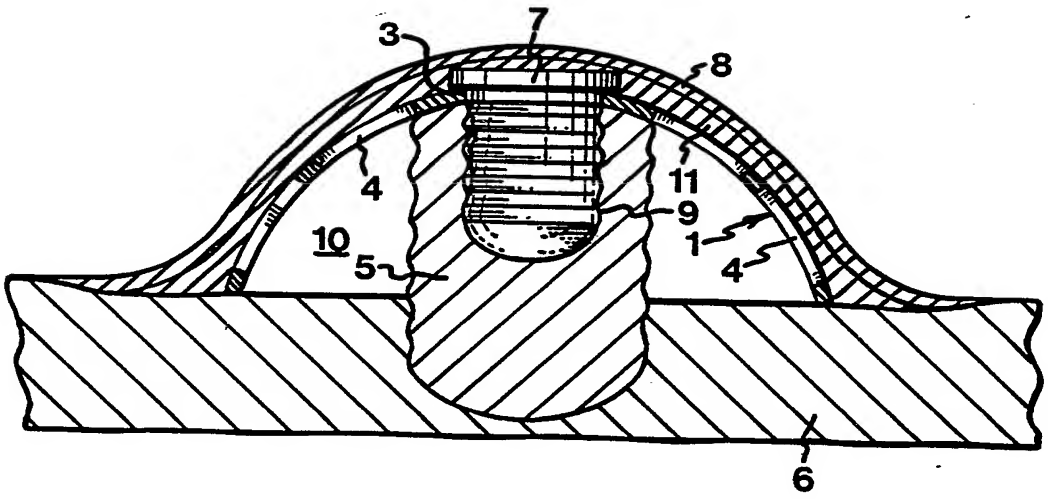

(57) Abstract

A method for producing growth of bone tissue in man or in animals consists in releasing a flap from the bone tissue in the area where growth is to take place; a bleeding being produced. Then, the flap is put back over the bone tissue and maintained at a distance therefrom, whereby a space for the blood from the bleeding is formed between the bone tissue and the flap. A device for implementing the method consists of a tissue-compatible and inert material and comprises a domed, perforated element of slight thickness and attachment means. A device for efficiently anchoring an implant (5) in bone tissue (6) has the shape of a perforated calotte (1), the lower periphery (2) of which defines a surface much larger than the cross-sectional surface of the implant (5). Further, the device is formed with an opening (3) which enables it to be mounted on the implant. A method for securely anchoring an implant is also described.

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METHOD AND DEVICE FOR EFFICIENTLY ANCHORING AN IMPLANT, AND METHOD AND DEVICE FOR PROMOTING GROWTH OF BONE TISSUE

The invention concerns a method and a device for producing growth of bone tissue, as well as a device for securely anchoring an implant in bone tissue by producing growth of bone tissue.

When the teeth in a jaw are lost, the jawbone begins to resorb, which is inconvenient when the lost teeth are to be replaced with false teeth in the form of removable or anchored dentures.

If the jawbone is much resorbed, it may be difficult to make removable dentures remain in place. Further, it may be impossible to anchor a bridge in the jawbone, since this requires a certain minimum thickness of the jawbone in order that the fixtures in which the bridge is screwed can be implanted therein. The minimum thickness of the jawbone must be such that the fixtures can be implanted in their entirety, so that their uppermost end is on a level with the interface of the jawbone with the mucous membrane which otherwise runs the risk of being perforated thereby. In the upper jaw, the jawbone must, furthermore, be at least so thick that there is no risk of the fixtures penetrating into the sini, which might lead to inflammation causing the fixtures to come loose. In the lower jaw, the jawbone must be at least so thick that there is no risk of the fixtures perforating canalis mandibularis (see Fig. 3, Item 12), since this may cause the patient to lose his sensibility in the lower lip. Moreover, the fixtures must, if to be usable, have a certain minimum length. Very short fixtures (3-5 mm) are not sufficiently anchored in the bone and may therefore come loose when subjected to load.

To enable use of bridges when the jawbone is resorbed to such an extent that fixtures cannot be anchored therein, enough jawbone must be recreated to enable anchoring.

In a prior art method, part of the patient's iliac crest or rib is transplanted to the jaw. The transplanted bone is treated to fit the jaw, and is then screwed onto the existing jawbone by means of fixtures, whereupon the mucous membrane is applied and sewn on. As to the upper jaw, the bone transplant can also be placed in the maxillary sini (Fig. 3, Item 13) to which access is gained by drilling through the buccal bone wall. Then, dentures may be attached in the thus-restored jaw. However, this method is not only expensive, care-demanding and extremely unpleasant to the patient (in particular old people may suffer from postoperative complaints from the hip), but it is also disadvantageous in that the transplanted bone is gradually resorbed.

A method for filling out defects in the jawbone consists in building up the resorbed jawbone with the aid of non-resorbing, bone-like material, e.g. hydroxylapatite. This technique is described in the article "Projection of Alveolar Ridge Deficiencies with Nonresorbable Hydroxylapatite", in the Journal of the American Dental Association, Vol. 105, December 1982, pp 993-1001.

Guided tissue regeneration is a known technique for creating new periodontal tissue for real teeth. This technique is based on the assumption that only some of the cell types in the jaw have a positive effect on the creation of supporting tissue, whereas other types have a negative effect. The latter, i.e. the epithelium, connective tissue and bone cells, should be prevented from reaching the tooth, whereas the former, mostly from the periodontal ligament, should have free access thereto. To keep away the undesired cells, "cell-tight" filters or membranes placed near to the tooth are used. The membrane, which is soft, is applied or applies itself to the tooth. A much-used membrane consists of expanded PTFE and is sold under the tradename of GORE periodontal membrane (Gottlow et al J. Clin. Periodontology 1984; 9: 494-503; Pontoriero, R. et al J. Clin. Periodontology 1988; 15:

247-254; Pontoriero, R. et al J. Clin. Periodontology 1989;: 16: 170-174; Gottlow, J. et al 1986; 13: 604-616; Becker, W. et al Int. J. Periodont. Rest. Dent. 1988; 3: 2-16).

When modified, this technique is said to be useful in connection with fixtures. The flat membrane is applied to the top of the fixture, under the flap (Dahlin et al Int. J. Oral Maxillofac. Implants 1989; 4(1):19-25; Becker, W. et al Int. J. Periodont. Rest. Dent. 1990; 10: 93-102). We have, however, found that this technique gives no satisfactory regeneration of bone tissue.

Also in areas other than teeth prosthetics, there are problems with replacing parts of the skeleton that have lost their original shape. After a traffic accident, crushed or caved-in skeleton parts of the face may have to be replaced, and in bone neoplasm therapy, it is sometimes necessary to surgically remove skeleton parts which may need to be replaced.

One object of the invention is to obviate the above inconveniences by providing a method and a device promoting growth of bone tissue.

Another object of the invention is to provide a method and a device for securely anchoring an implant in bone tissue.

These objects are achieved by the methods and devices recited in the appended claims.

According to the invention, it has surprisingly been found that soft, cell-tight membranes are not suitable for recreating bone tissue at fixtures, i.e. coronally of (above) the surrounding bone level. In our experience, cells in the jaw that previously were considered disadvantageous in the recreation of bone tissue are actually extremely advantageous in this process. According to the invention, bone cells from the periosteum and the bone edge are given access to the operation area round the fixture. The accessibility is created by the rigidity and the perforations of the device. According to the inven-

tion, it has been proved necessary to create a protected space round the fixture for bone regeneration. In addition, the device used for this purpose serves to obviate the risk of the fixture perforating the flap which, by means of this device, is kept away from the fixture. The perforations of the device permit rapid and adequate revascularisation of the blood clot, so that this does not degenerate before newly-formed blood vessels and bone cells from bone tissue and periosteum have had time to grow in. They increase the oxygen and nutrient supply necessary for the regeneration process.

Embodiments of the invention will be described in more detail below, reference being had to the accompanying drawings, in which

Fig. 1 is a perspective view of an inventive device especially suited for securely anchoring tooth implants,

Fig. 2 is a cross-sectional view of the device in Fig. 1 mounted on a tooth implant in a jaw,

Fig. 3 illustrates how the device can be used, both in the oral cavity and in the maxillary sinus after loosening the mucous membrane,

Fig. 4 is a schematic view of part of a face with an embodiment of the inventive device for producing growth of the cheekbone,

Figs 5a-c illustrate how the device can be used for reconstructing jawbone resorbed after tooth extractions, Fig. 5a being a top view, Fig. 5b being a sectional view, and Fig. 5c being a front view, and

Figs 6-8 illustrate the results of a fixture installation without a calotte, with a perforated calotte according to the invention, and with a non-perforated calotte.

Fig. 1 shows a device for securely anchoring an implant in bone tissue. This device is especially suitable for fixtures used for permanently anchoring dentures in the jawbone.

The device shown, generally designated 1, substantially has the form of a calotte. Its lower periphery 2 is rounded and, in the embodiment shown, substantially circular, but it may also be oval. The calotte may be semi-spherical or, as in the Figure, truncatedly semi-spherical. At the top of the calotte, there is a central opening 3.

The calotte is made of a tissue-compatible and inert material, preferably titanium. Other suitable materials include ceramic materials, e.g. frialite, steel, plastics and hydroxylapatite. The thickness of the calotte is preferably so small in relation to the size that the calotte is mouldable in the plane of the lower periphery. However, the thickness should be sufficient to make the calotte vertically rigid. A device intended for securely anchoring a fixture and having a diameter of about 7 mm at the lower periphery 2, may suitably have a thickness of about 0.1 mm.

The embodiment shown in Fig. 1 is formed with perforations 4, which may take up more or less of the surface of the calotte across which they are distributed.

In Fig. 2, the device 1 of Fig. 1 is mounted on a fixture 5 which is screwed into bone tissue 6 by means of a screw 7. The diameter of the opening 3 is smaller than that of the cross-sectional surface of the fixture 5, thus enabling the device to rest on the upper side of the fixture 5.

In the following, one mode of the method according to the invention will be described in connection with the anchoring of a fixture in a much-resorbed jawbone.

In the inventive method, the area of the resorbed jawbone in which the fixture is to be attached is first uncovered by cutting away the flap, i.e. the mucous membrane and the periosteum normally covering the jawbone (designated 8 and 11 in Fig. 2), from the bone and folding it aside. Then, a hole is prebored in the jawbone, and a fixture 5 is screwed into the bone as far as the thickness

thereof permits.

If no further measures were taken, the fixture would not, after healing, be able to withstand the strain from a bridge attached to the fixture, since it is not screwed into a sufficiently thick jawbone. With the inventive method and device, it is, however, possible to produce growth of the bone tissue 6, thereby achieving satisfactory anchoring. For this purpose, one chooses a device 1 of the type shown in Fig. 1, the lower periphery 2 of which defines an area much larger than the cross-sectional area of the fixture 5. As an example, it may be mentioned that fixtures usually have a diameter of 3-4 mm, and that the recommended centre-to-centre distance between the fixtures is 7-8 mm. This means that the device 1 must not extend more than about 7 mm in "the direction of the jaw", if it is to be possible to provide adjoining fixtures with the inventive device.

Then, the device 1 is attached to the fixture 5 by means of a screw 7, which is screwed into the internal thread 9 in the fixture 5. The device forms a calotte over the fixture 5, a space 10 being formed between the calotte, the bone tissue 6 and the fixture 5. This space will immediately be filled with blood from bleedings arising upon the uncovering of and the drilling in the bone tissue. When the calotte 1 has been positioned, the flap is placed over the device 1 and the fixture 5, and is then sewn onto the surrounding tissue.

In a couple of months, cells from the bone tissue 6 and the periosteum 11 will grow into the space 10, whereby the fixture 5 is securely anchored. When the space 10 is entirely filled with bone tissue, the flap may again be loosened, the screw 7 removed, and a bridge anchored in the fixture 5 and the adjoining fixtures, which as well may be anchored by means of devices according to the invention. The fixture 5 thus anchored is able to withstand load from the bridge, being completely anchored in the bone tissue 6.

The device 1 need not be removed after growth of bone has taken place. Since the device is made of a tissue-compatible and inert material, it may safely be left in the jaw. If one so wishes, it is nevertheless possible to remove the device when the desired bone growth has been achieved.

As mentioned above, the device 1 is preferably mouldable. This is an advantage if the jawbone in which the fixture 5 is to be attached is so narrow that the periphery 2 of the device is outside the jawbone when the device has been mounted on the fixture, or if the shape of the jawbone otherwise does not match the device 1. In such a case, the device 1 may easily be adapted to the jawbone at issue. As already mentioned, the device should however be vertically rigid, the reason being that it, in our view, is essential that the blood clot in the space 10 remains still, in order to avoid the formation of connective tissue. Many patients have to use removable dentures during the healing process, and if the device is not vertically rigid, the load from these dentures may cause the clot to move, thus disturbing it.

Fig. 4 shows an embodiment of the inventive device used for recreating or newly creating cheekbone by bone growth. In this case, the device comprises a curved, mouldable but vertically rather rigid element of slight thickness. The device 14 has rounded edges in order not to damage surrounding tissue. As in Fig. 1, the device is perforated to enable oxygen and nutrient supply to the blood clot in the space defined by the device. Further, the device is formed with peripheral openings 16 for attachment means, optionally in the form of pins 15 (cf. Fig. 5c), which fix the device in the bone tissue round the area where growth of bone tissue is to be produced.

The device is used roughly in the same manner as described above. The area where bone growth is to be produced, is uncovered by cutting away the flap. Then, the device, which has been shaped so as to correspond to the

shape desired for the created bone tissue, is fixed by means of the pins 15 in the existing bone tissue. Thereafter, the flap is put in place over the device and sewn on. After about 6 months, bone growth has been achieved in the space beneath the device.

Fig. 5a shows an upper jaw from above. The continuous lines illustrate the extension of the existing jawbone, and the broken line illustrates the perforated, self-supporting (rigid) device 14 which keeps out the soft tissue and promotes bone growth in the space 10. Fig. 5b illustrates the same jaw, but in profile, and Fig. 5c shows the perforated device from the front. The same reference numerals as before are used. With this device, a much more aesthetical appearance can be obtained. Thus, the lip is pushed out, and the sunken, aged looks of the patient are radically changed. The prosthesis replacing the lost teeth is connected to the underlying mucous membrane in an aesthetical manner.

In a study of dogs, the importance of creating space and the significance of the perforations were tested. After extracting the premolars of two dogs, these areas were left to heal for 8 weeks. The mucoperiosteum flaps were unfolded, and an implant was installed in each lower-jaw quadrant of the dogs. Thus, 6 mm of the 10-mm fixtures used were mounted in bone, thereby leaving 4 mm of the fixtures above the bone level. The alternatives no calotte, a perforated calotte of titanium, and a non-perforated calotte of titanium were tested. Without a calotte, the fixture penetrated the mucous membrane (Fig. 6). With a perforated calotte, a growth of what is clinically referred to as bone took place and comprised the entire internal surface of the calotte (Fig. 7). With a non-perforated calotte, there was a minimal, slightly ridge-shaped regeneration of bone along the periphery of the calotte. The main part of the fixture was not covered by any tissue, which indicates that the clot had been

destroyed and resorbed (Fig. 8). These results were all established after 3 months.

It is possible to further promote the bone growth by treating the calotte with growth-promoting substances, e.g. bone build-up factors.

CLAIMS

1. A method for producing growth of bone tissue in man or in animals, c h a r a c t e r i s e d in that a flap is released from the bone tissue to uncover the latter in the area where growth is to take place, a bleeding being produced in this area, and that the flap is put back over the bone tissue and maintained at a distance therefrom, whereby a space for the blood from the bleeding is formed between the bone tissue and the flap.

2. A device for promoting growth of bone tissue in man or in animals, c h a r a c t e r i s e d in that it is arranged to be placed between the bone tissue whose growth is to be promoted and the flap normally covering the bone tissue, that it consists of tissue-compatible and inert material, and that it comprises a domed, perforated and vertically rigid element (14) of slight thickness, the outside of said element being arranged to be in contact with the flap, and the inside being arranged to face the bone tissue to produce a space between said element and the bone tissue, and attachment means (12) for fixing said element in the bone tissue.

3. The device of claim 2, c h a r a c t e r i s e d in that it consists of titanium.

4. A device for securely anchoring an implant (5) in bone tissue (6), c h a r a c t e r i s e d in that it has essentially the form of a perforated and vertically rigid calotte (1; 14) with a lower periphery (2) defining a surface much larger than the cross-sectional surface of the implant (5), that it consists of tissue-compatible and inert material of slight thickness, and that it has means (3) which enable it to be mounted on the implant.

5. The device of claim 4, c h a r a c t e r i s e d in that it consists of titanium.

6. The device of claim 4 or 5, c h a r a c t e r - i s e d in that it is mouldable in the plane of the lower periphery.

7. A method for securely anchoring an implant in bone tissue, c h a r a c t e r i s e d in
that a flap is released to uncover the bone tissue in the area where the implant is to be anchored,
that a hole is drilled in the bone tissue,
that an implant is screwed into the hole,
that the device of claim 4 is produced,
that said device is mounted on the implant, and
that the flap is put over said device and the implant, and sewn onto the surrounding tissue.

FIG.1

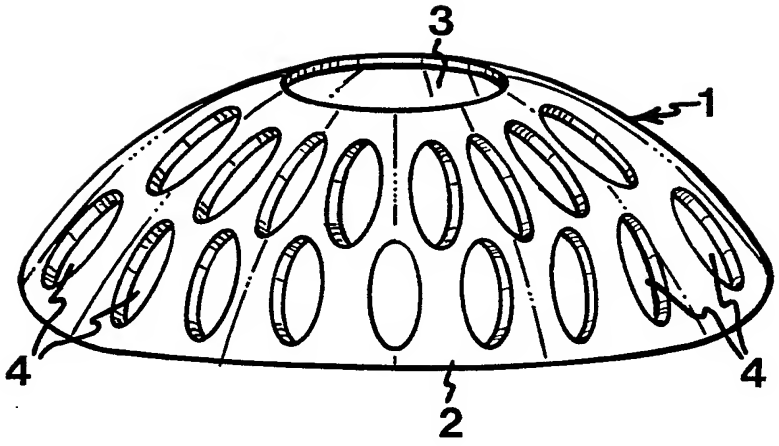

FIG.2

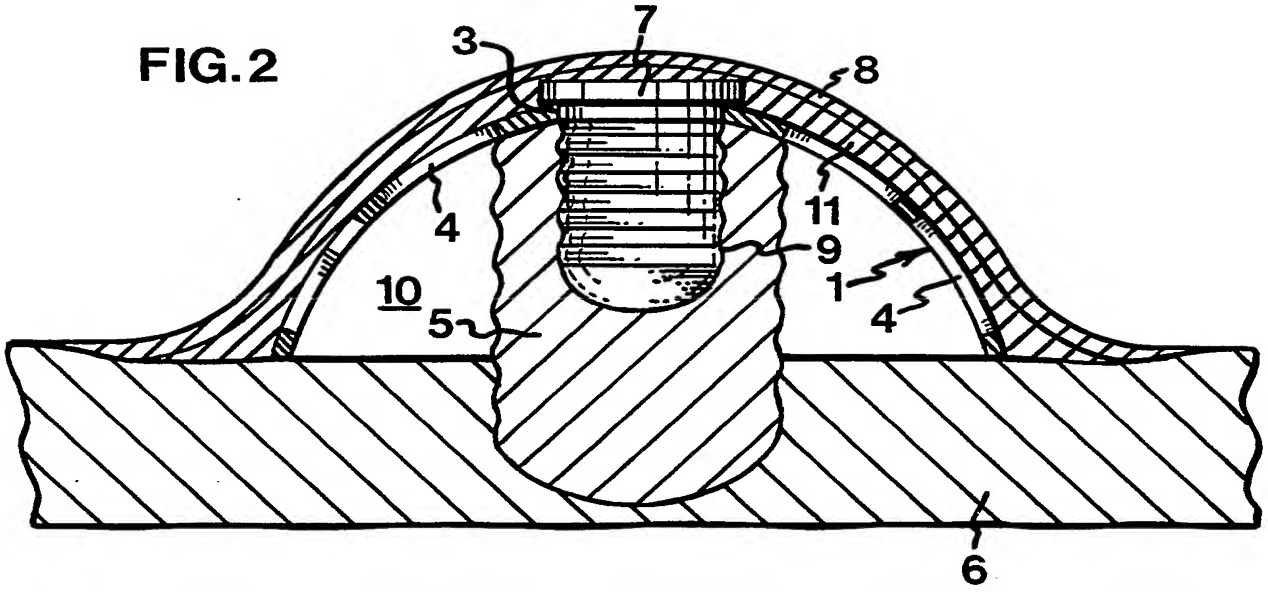

FIG.4

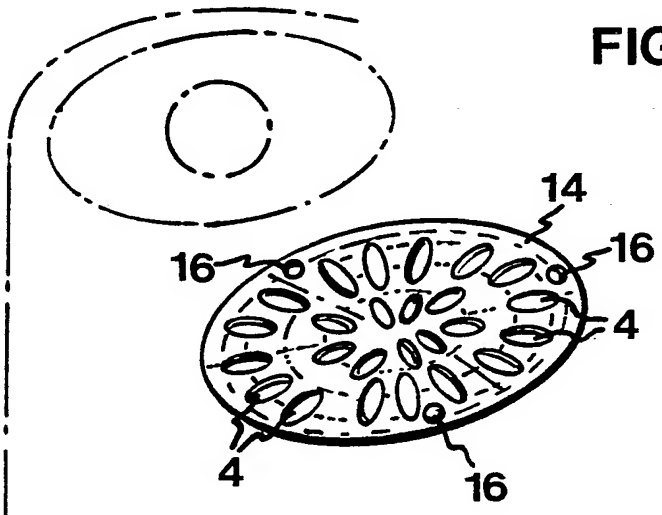

FIG.3

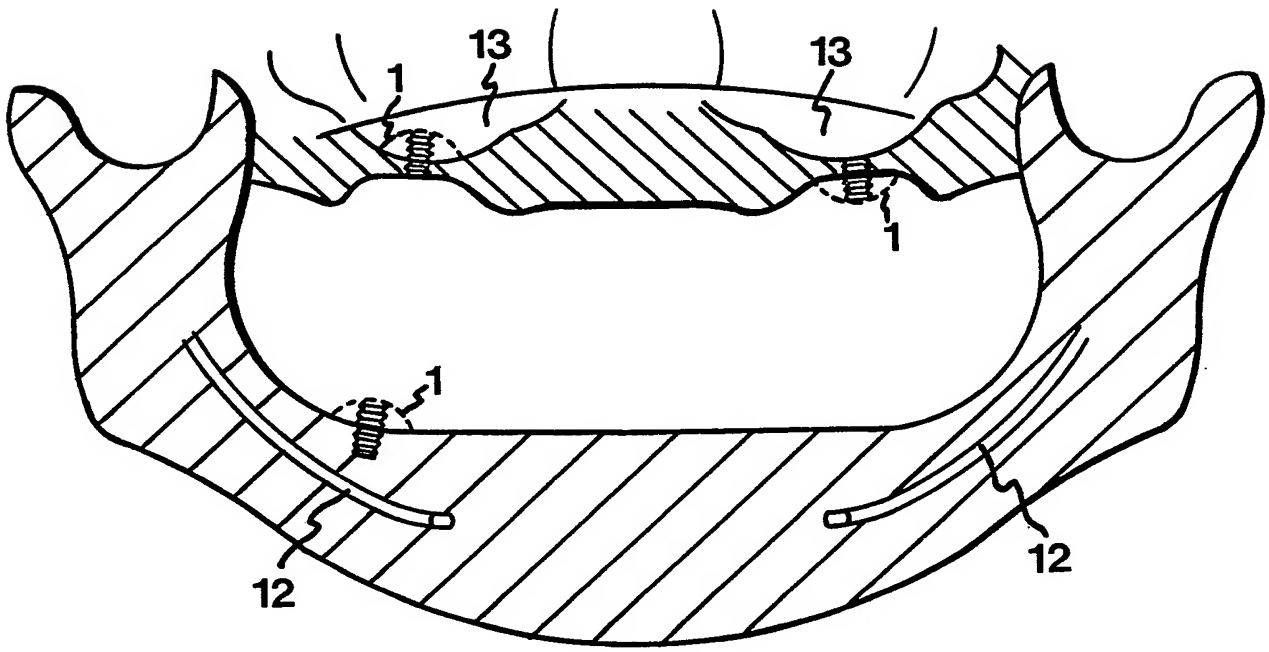

FIG.5a

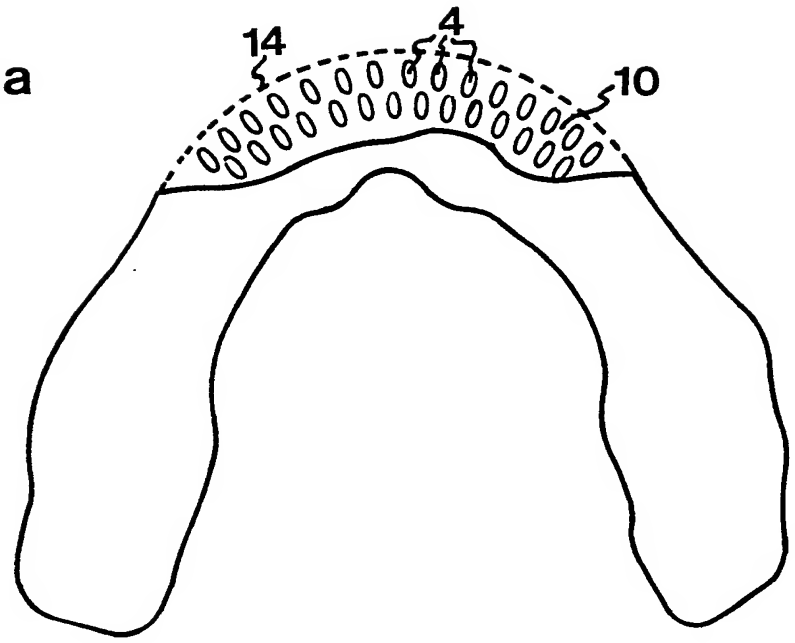

FIG.5b

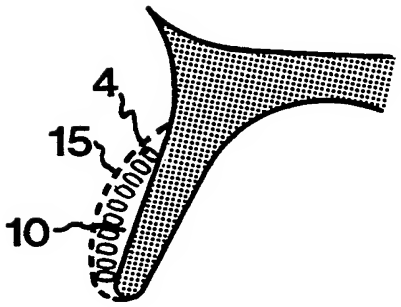

FIG.5c

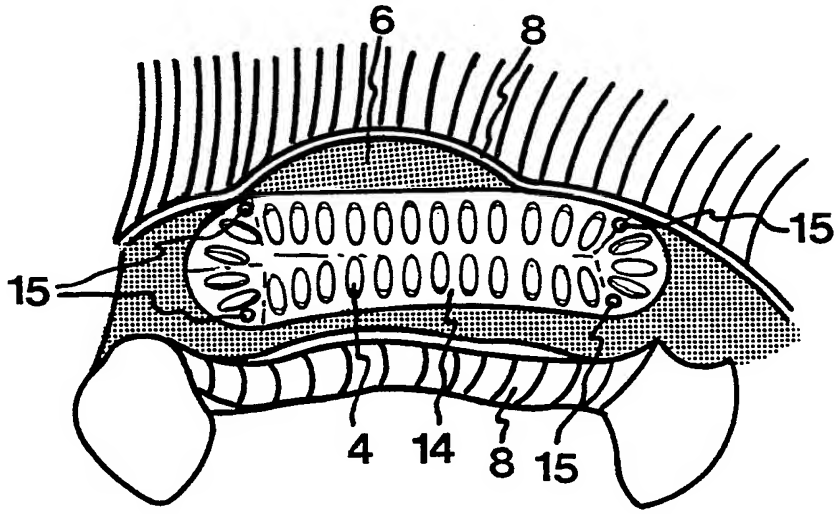

FIG.6

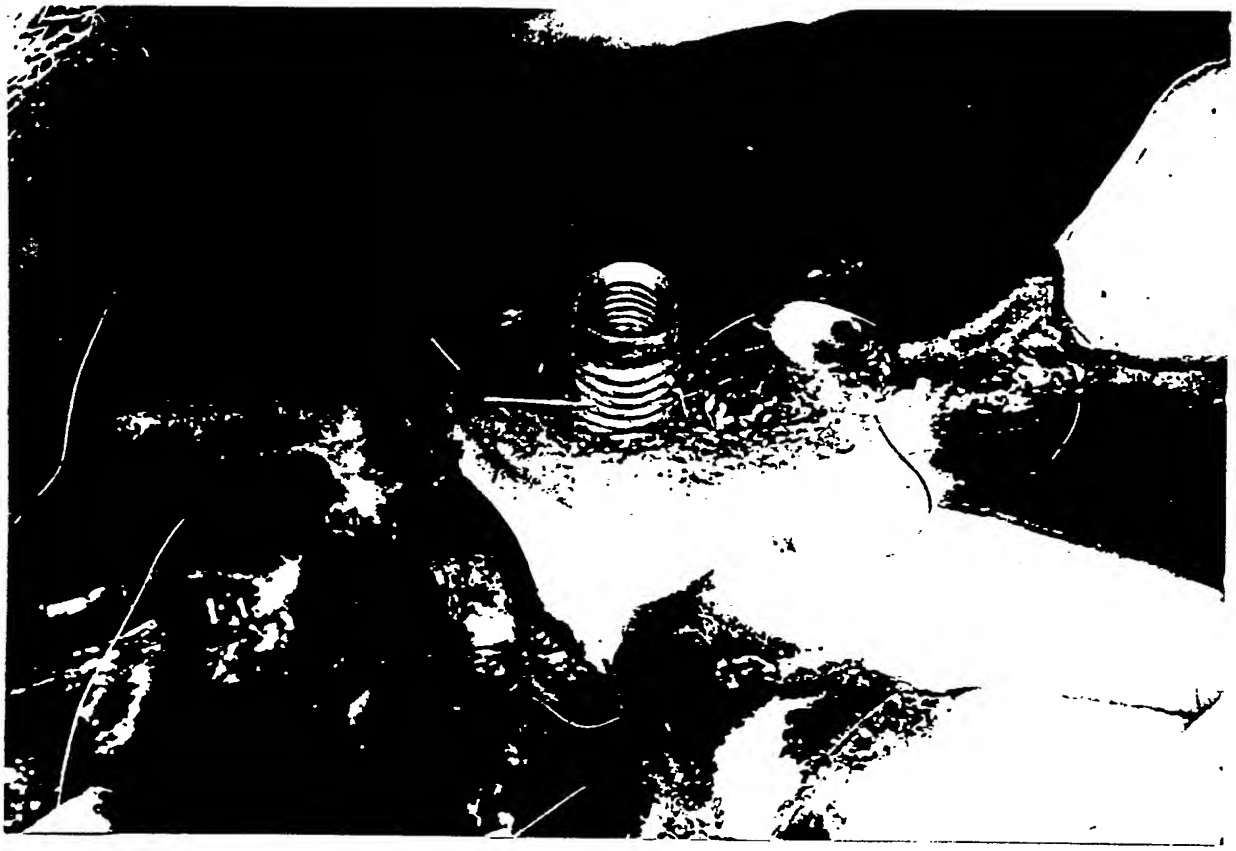

FIG.7

FIG.8

INTERNATIONAL SEARCH REPORT

International Application No PCT/SE 91/00216

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC5: A 61 C 8/00, A 61 F 2/02

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
IPC5	A 61 C; A 61 F

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in Fields Searched[8]

SE,DK,FI,NO classes as above

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

Category *	Citation of Document,[11] with indication, where appropriate, of the relevant passages[12]	Relevant to Claim No.[13]
A	WO, A1, 8600517 (W.L. GORE & ASSOCIATES, INC.) 30 January 1986, see the whole document --	2-6
A	WO, A1, 8602824 (LUNDGREN, DAN) 22 May 1986, see the whole document --	2-6
P,A	WO, A1, 9007308 (PROCORDIA ORATECH AB) 12 July 1990, see the whole document --	2-6

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* Special categories of cited documents: [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance, the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance, the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
13th June 1991	1990 -06- 17
International Searching Authority	**Signature of Authorized Officer**
SWEDISH PATENT OFFICE	Jack Hedlund

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V. [X] OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [1]

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. [X] Claim numbers 1...7..., because they relate to subject matter not required to be searched by this Authority, namely:

See PCT Rule 39.1(iv): Methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods.

2. [ ] Claim numbers....., because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claim numbers....., because they are dependent claims and are not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. [ ] OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [2]

This International Searching Authority found multiple inventions in this international application as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the the claims. It is covered by claim numbers:

4. [ ] As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additonal fee.

Remark on Protest

[ ] The additional search fees were accompanied by applicant's protest.

[ ] No protest accompanied the payment of additional seach fees.

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. PCT/SE 91/00216

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.
The members are as contained in the Swedish Patent Office EDP file on 91-04-30
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Patent document cited in search report	Publication date	Patent family member(s)		Publication date
WO-A1- 8600517	86-01-30	AU-B-	582773	89-04-13
		AU-D-	2866489	89-08-03
		AU-D-	2866589	89-06-08
		AU-D-	2866689	89-06-08
		AU-D-	4139985	86-01-09
		AU-D-	4540385	86-02-10
		CA-A-	1249459	89-01-31
		CA-A-	1255580	89-06-13
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		EP-A-B-	0171173	86-02-12
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